

AT



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,038	12/04/2001	Glenn R. Bowers	60116P1	2458

22847 7590 04/20/2004

SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,038	Applicant(s) BOWERS ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,14,16,17,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,14,16,17,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the Office action mailed 8 October 2003 is withdrawn.
2. Claims 1-5, 8, 14, 16-17 and 36-37 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 1-5, 8, 14, 16-17 and 36-37 under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of the statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement.

Claim Rejections - 35 USC § 112

5. Claims 8, 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to soybean seeds and tissue culture produced from soybean seeds wherein one parent plant of the seeds is not described in the specification; thus, the identity of the seeds remains unclear. Neither the second parent plant required required to make the seeds,

Art Unit: 1638

nor the seeds themselves are defined by genomic structure or by phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states:

[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

6. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 8 October 2003, as applied to claims 16 and 36, due to amendment of the claims. Applicant's filed no arguments to this rejection in the response of 7 April 2004.

Claim 36 lacks antecedent basis for the limitation "said progeny seed" in line 5.

Claim Rejections - 35 USC § 102 - 35 USC § 103

7. As Applicant responded to both rejections at the same time, they will be addressed together here, after a listing of the rejections.

8. Claims 1-5, 8, 14, 16-17 and 36-37 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Rhodes (1999, US Patent

Art Unit: 1638

5,942,666). The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 October 2003. Applicant's arguments filed 7 April 2004 have been fully considered but they are not persuasive.

9. Claims 1-5, 8, 14, 16-17 and 36-37 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Luzzi (2000, US Patent 6,084,159). The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 October 2003. Applicant's arguments filed 7 April 2004 have been fully considered but they are not persuasive.

Applicant urges that the ruling set forth in *In re Best* was misstated and a basis for believing that the products of the prior art and the applicant are the same has not sufficiently been established. Applicant urges that in *In re Best*, the rejection was based on the inherency doctrine; thus, inherency must be established (response pg 4-5).

This is not found persuasive. Because the plants of the instant application, S52-U3, and the plants taught by Rhodes, 9392379521283, share the same non-environmentally determined traits, including hilum color (buff), leaflet shape (ovate), pubescence color (gray), flower color (white), pod color (tan), plant habit (determinate), Maturity Group (V), Round-Up resistance, and resistance to soybean cyst nematode races 3 and 14, the plants are inherently identical.

Because the plants of the instant application, S52-U3, and the plants taught by Luzzi, 9524889614923, have the same non-environmentally determined traits, including hilum color (buff), leaflet shape (ovate), pubescence color (gray), flower color (white), pod color (tan), plant habit (determinate), Maturity Group (V), and Round-Up resistance, the plants are inherently identical.

Art Unit: 1638

Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Applicant urges that a reasonable basis for inherency has not been set forth (response pg 5).

This is not found persuasive. Given that the instantly claimed soybean plants are identical to the prior art soybean plants in all non-environmentally determined characteristics that are listed for both, a reasonable basis for inherency has been set forth.

Applicant urges that the production of soybean cultivars have distinct genotypes is highly unpredictable, because breeder's selection occurs in unique environments, with no control at the DNA level, and with millions of different possible genetic combinations generated; a breeder cannot predict the final resulting lines and cannot produce the same cultivar twice, even using the same parents and same selection techniques (response pg 5-6).

This is not found persuasive. Applicant has not presented evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. For example, Applicant has not shown that S52-U3 is susceptible to *Phytophthora megasperma* var *sojae* races 1, 3, 4, 5, 6, 7, or 9, which would demonstrate that S52-U3 is different from the plant claimed in '666.

Applicant urges that neither '666 nor '159 discloses that the cultivars used to develop those plants were the same as those used to develop S52-U3, and even if they were identical, the inventors could not have produced the same cultivar. Applicant urges that even though the

Art Unit: 1638

soybean plants possess grossly similar characteristics, each has a unique genotype and breeding is unpredictable; the basic nature of the claimed subject matter is patently different (response pg 6).

This is not found persuasive, as the disclosed characteristics are identical for the instantly claimed and prior art plants. It is noted that Applicant also did not list the cultivars used to develop the instantly claimed plants.

Applicant urges that the prior art has not been shown to necessarily function in accordance with the claimed limitations but merely shows a probability or possibility of inherency (response pg 6).

This is not found persuasive because all the recited non-environmentally determined characteristics are identical. See *In re Best* 195 USPQ 430, 433 (CCPA 1977)

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product ... Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

The US Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs, and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (571) 272-0547.

Anne R. Kubelik, Ph.D.

April 14, 2004

A handwritten signature in cursive script, appearing to read "Anne R. Kubelik".

ANNE KUBELIK
PATENT EXAMINER